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Increasing goals of care conversations in primary care: Study protocol for a cluster randomized, pragmatic, sequential multiple assignment randomized trial

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethics

This study has been approved by the VA Central Institutional Review Board #E21–04 and is registered at ClinicalTrials.gov (NCT05001009).

Disclaimer

The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

CRediT authorship contribution statement

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Abstract

Background: Goals of care conversations explore seriously ill patients' values to guide medical decision making and often inform decisions about life sustaining treatments. Ideally, conversations occur before a health crisis between patients and clinicians in the outpatient setting. In the United States Veterans Affairs (VA) healthcare system, most conversations still occur in the inpatient setting. Strategies are needed to improve implementation of outpatient, primary care goals of care conversations.

Methods: We plan a cluster randomized (clinician-level) sequential, multiple assignment randomized trial to evaluate the effectiveness of patient implementation strategies on the outcome of goals of care conversation documentation when delivered in combination with clinician implementation strategies. Across three VA healthcare system sites, we will enroll primary care clinicians with low rates of goals of care conversations and their patients with serious medical illness in the top 10th percentile of risk of hospitalization or death. We will compare the effectiveness of sequences of implementation strategies and explore how patient and site factors modify implementation strategy effects. Finally, we will conduct a mixed-methods evaluation to understand implementation strategy success or failure. The design includes two key innovations: (1) strategies that target both clinicians and patients and (2) sequential strategies with increased intensity for non-responders.

Conclusion: This study aims to determine the effect of different sequences and combinations of implementation strategies on primary care documentation of goals of care conversations. Study partners, including the VA National Center for Ethics in Health Care and Office of Primary Care, can consider policies based on study findings.

Keywords

Goals of care conversations; Advance care planning; Serious illness conversations; Implementation science; Sequential multiple assignment randomized trial (SMART); Quality of life; Palliative care

1. Background

Early goals of care conversations or advance care planning (ACP) in patients with serious illness are associated with improved patient and caregiver outcomes [1]. Goals of care

conversations are a communication process in which a clinician and patient and/or their health care surrogate decision-maker discuss patient values and preferences for current and future medical care with the goal of aligning care with their wishes. Patients and families prefer these conversations occur before a health crisis, ideally with clinicians with whom they have an established relationship. [2–5] A National Academy of Medicine report called for these conversations to be a part of standard patient-centered care in the outpatient setting [6]. A key gap in the literature is how to successfully implement goals of care conversations/ACP in real world settings, specifically for patients with serious illness.

To encourage and document goals of care conversations in the VA, in 2017 the VA implemented the Life-Sustaining Treatment Decisions Initiative (LSTDI) [7]. The LSTDI includes a goals of care conversation with patients and subsequent documentation of this conversation in a standardized electronic health record note (Table 1). For primary care clinicians, this note is linked with orders for life-sustaining treatments (LSTs) [7].

While the exact timeframe of “early” goals of care conversations may vary, ideal implementation of the LSTDI would result in goals of care conversations in the outpatient setting while the Veteran has decision making capacity and can express his/her wishes and avoid unwanted hospitalizations or undesired intensive care at the end of life. [7,8] However, years after LSTDI implementation, 60% of VA goals of care conversations still occur in the inpatient setting near end of life, not earlier in the course of serious illness in the outpatient setting, which is the goal of the LSTDI policy and represents high quality care.

Based on our prior research and in collaboration with local leaders, clinicians and our operations partners [9–12], we decided to initially evaluate the effectiveness of low intensity versions of our implementation strategies to support the implementation of the LSTDI, and if ineffective, subsequently evaluate higher intensity strategies that include more clinician and patient interaction. This approach allows us to: (1) replicate the real-world setting, determining whether in some cases a modestly intensive implementation strategy requiring few resources could be effective, and (2) learn which sequence of strategies is most effective overall and which sequence(s) is most effective for specific patients or medical center settings.

We use a Sequential Multiple Assignment Randomized Trial (SMART) design which is an adaptive design with more intensive predefined interventions for non-responders [13].

An objective of this SMART study is to determine the best combination of low and high intensity patient implementation strategies, when given in combination with clinician implementation strategies, to improve the occurrence of documented goals of care conversations in Veterans with serious medical illness. Four design features provide generalizable knowledge by: (1) Applying a SMART design to test implementation strategies, (2) balancing a pragmatic, point of care approach with the need to address multiple barriers to implementation, (3) addressing the need to improve implementation of a national VA health system policy, and (4) addressing both patient and clinician barriers to implementation using a participatory approach (Table 2).

2. Methods

2.1. Study design

Applying the SMART design to test different implementation strategies for increasing goals of care documentation in the outpatient setting is novel (Fig. 1). In this SMART, randomization is at the clinician level to minimize within-clinician contamination and the outcomes are at determined at the patient-level. Patients will receive sequential randomized implementation strategies, and clinicians will all receive the same sequential implementation strategies. In Stage 1, clinicians along with their patient panels are randomized. The patient panels will randomly receive either no patient engagement or low intensity patient engagement. All clinicians will receive the low intensity clinician implementation intervention in Stage 1. At the end of the Stage 1, clinicians will be defined as responders if they wrote at least 4 LST notes. Patient panels of clinician responders will not be re-randomized and will not receive any patient-level implementation strategies during Stage 2. Clinicians deemed non-responders (fewer than 4 LST notes) and their patient panels will be randomized to receive either low intensity or high intensity patient engagement in Stage 2. All clinicians, regardless of responder or non-responder status, will be exposed to the high intensity clinician implementation intervention during Stage 2. No new patients will be added when moving to Stage 2. For Stage 1, we plan a 6-month study period, and for Stage 2 we plan a 9-month study period. This study design allows us to use a patient-level binary outcome of documentation of goals of care conversations to understand the effectiveness of different sequences of implementation strategies.

The overarching hypotheses include:

Hypothesis 1 (first stage of SMART): Compared to a low intensity clinician implementation strategy alone, a low intensity clinician implementation strategy combined with a low intensity patient implementation strategy will lead to increased documentation of goals of care conversations.

Hypothesis 2 (second stage of SMART): Among those who do not respond to low intensity implementation strategies, compared to a high intensity clinician implementation strategy paired with a low intensity patient implementation strategy, a high intensity clinician implementation strategy combined with a high intensity patient implementation strategy will lead to increased documentation of goals of care conversations.

2.2. Conceptual foundation

Published literature [14], our preliminary studies [9,15,16], and the Practical, Robust Implementation and Sustainability Model (PRISM) inform key barriers and implementation strategies to improve outpatient goals of care conversations. PRISM is a conceptual framework that integrates key elements for successful implementation intervention design, predictors of implementation and diffusion, and outcome measures [17]. PRISM identifies four contextual domains to have potential impact on implementation success: 1) Organizational and patient perspectives on the intervention and/or implementation intervention; 2) Organizational and patient (recipients) characteristics; 3) Implementation

and sustainability infrastructure (e.g., training, support); and 4) External environment (e.g., policies and priorities outside the study setting). PRISM also identifies a set of outcomes highly relevant to implementation and scale up efforts, including reach, effectiveness, adoption, implementation, and maintenance [18]. We chose PRISM because it was created in the context of healthcare and has a comprehensive and yet pragmatic approach that integrates multi-level and multi-partner influences on a diverse set of implementation outcomes.

2.3. Setting

The study will be conducted in three VA health systems, VA Eastern Colorado (includes two medical center-based and two community-based outpatient clinics), Greater Los Angeles (medical center-based clinics), and Palo Alto (medical center-based and one community-based outpatient clinic). These sites were chosen to reflect variable primary care contexts (e.g., staffing levels, stability in primary care leadership).

2.4. Participants

2.4.1. Clinicians—The clinician unit of randomization will be primary care providers (PCPs) eligible to complete LST notes and orders. PCPs include physicians, osteopaths, nurse practitioners, physician assistants. PCPs will be eligible for randomization if they have at least 15 eligible patients without LST notes in the electronic health record (to allow for clinician improvement and ample opportunity for documentation) and have written fewer than 4 LST notes in the prior 6 months. In addition to PCPs, the primary care team implementation strategies include primary care nurses and social workers.

2.4.2. Patients—Among eligible PCPs, we include their patients in the top 10th percentile of risk for hospitalization and death at time of enrollment with cancer, heart failure (HF), chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), end-stage renal disease (ESRD), dementia, or end-stage liver disease (ESLD). Illnesses will be determined based on diagnosis codes for cancer [19], HF [20,21], COPD [22], ILD [23], ESRD [19], dementia [24,25], and ESLD [26]. The top 10th percentile of risk is determined using the VA Care Assessment Need (CAN) score of ≥90 using the one-year combined hospitalization/mortality variable. The CAN score is a valid prognostic measure created to help primary care proactively identify and manage at risk Veterans on a population level [27].

2.5. Recruitment

All participants will be identified through the VA Corporate Data Warehouse which includes all study data. Clinician participation involves attendance at educational trainings which will be conducted at existing primary care meetings where clinician attendance is already expected. We will track clinician attendance and any clinician opt-out from educational trainings (which is unexpected) at the beginning of the study and exclude them from analysis. Patient participation involves opting-in to view educational information about goals of care conversations, as participating in goals of care conversations is part of the existing VA LSTDI policy.

2.6. Implementation strategies

Implementation strategies were developed for clinicians and patients to address barriers to implementation with input from primary care clinicians and leaders and patients (Table 3) [10–12]. The clinician implementation strategies were designed to address clinician and organizational barriers to LSTDI implementation, including (1) lack of clarity in how to identify patients with serious medical illness with whom to have a goals of care conversation, and (2) variability in leadership support, primary care clinician interest, and time to conduct a goals of care conversations. The patient implementation strategies aim to prepare patients for goals of care conversations [28]. A detailed description of the implementation strategies is provided in Tables 4 and 5 [29].

2.6.1. Clinician implementation strategies (Table 4)

2.6.1.1. Low intensity.: The clinician low intensity implementation intervention is a "booster" of the established LSTDI implementation intervention. In a single 30- to 50-min meeting, primary care clinicians will be presented with a summary and electronic materials on the LSTDI. We will provide online and local in person training options and when and how to complete goals of care conversations and documentation.

2.6.1.2. High-intensity.: The clinician high intensity implementation intervention includes engaging leadership and champions, modeling and facilitating site specific team processes and planning, monitoring progress, and reflecting on challenges. Primary care clinicians, nurses and social workers will be introduced to team based implementation strategies in three 30- to 40-min workshops. We will also email a "nudge" to primary care by sending a list of eligible Veterans who have upcoming primary care appointments. The "nudge" emails will include feedback on progress as well as patients identified who are interested in ACP outreach based on the phone calls to patients, which are part of the high-intensity patient implementation intervention (described in more detail in the next section).

2.6.2. Patient implementation strategies: patient engagement (Table 5)—

To prepare patients to be active participants in goals of care/ACP conversations, we will use PREPAREforYourCare.org (PREPARE), a patient-facing, evidence-based, online, interactive program. The program features video stories that guide users to explore their health care goals and wishes and learn how to discuss them with family, friends, and clinicians. The program also includes several easy-to-read written materials, including a pamphlet of the website content, a question guide, and a "Summary of My Wishes." In randomized clinical trials [30,31], PREPARE improved patient readiness to engage in advance care planning and documentation of advance directives.

2.6.2.1. Low-intensity.: At the start of the study, we will mail a PREPARE packet. The packet includes letters signed by primary care clinic leadership asking Veterans to view the PREPARE website and included printed materials, bring their "Summary of My Wishes" produced by the website, and talk about their wishes with their clinician at their next visit. The letter was tailored based on feedback from primary care clinicians and Veterans and was the same across all sites, but with different signatories as appropriate. As some Veterans may not go to the website, and to ensure equal access to PREPARE information, in the

mailing packets, we will also include the PREPARE pamphlet containing key points from the website and a Question Guide that contains key elements of goals of care conversation notes that patients can bring to clinic.

2.6.2.2. High-intensity.: In addition to mailing the PREPARE packet, study personnel will call patients to further encourage use of the PREPARE materials and to talk with their primary care team about their wishes for care.

2.6.3. Fidelity—Fidelity monitoring will assess the extent to which processes were completed in the clinician and patient implementation strategies. For clinicians, the percent of clinicians who attend the workshops will be measured. For patients, we will document the percent of eligible patients (1) who were sent a letter about goals of care conversations in both stages, (2) who received PREPARE materials via mail and who viewed the PREPARE website in both stages, and (3) who received telephone outreach in stage 2 among Veterans randomized to the high intensity patient intervention.

2.7. Outcomes

2.7.1. Primary outcome—The primary outcome is whether a goals of care conversation note was documented in Stage 2, among patients attributed to a clinician randomized in Stage 2. This was chosen as the primary outcome since the highest intensity clinician and patient implementation strategies are evaluated in Stage 2. The time frame for this outcome is from the start of Stage 2 to 9 months later.

2.7.2. Secondary outcomes—Secondary outcomes include whether a goals of care conversation note was documented at any point during Stage 1 or Stage 2 among all patients in the study (2a). Another secondary outcome is whether a goals of care conversation note was documented in Stage 1 among all patients in the study (2b).

2.7.2.1. Data.: Data will be collected from the VA Corporate Data Warehouse which serves as a repository for VA electronic health record data. New documentation of goals of care conversations will be measured at the end of Stage 1 and the end of Stage 2.Two note types that are routinely used within the VA as part of the VA's LSTDI Initiative will be captured and include: (1) "Goals and preferences to inform life-sustaining treatment decisions" (which can be used by most clinicians including social work or nursing to document conversations relevant to the patient's goals, values, and preferences) and (2) "Life-sustaining treatment" notes and associated orders (completed by clinicians authorized to write orders for life-sustaining treatments based on goals of care conversations), will be captured. We focus on these notes since they are immediately accessible on the central "postings" section of the medical record and easily found at the point of care. Other documentation of goals and values (e.g., in progress notes) is not easily searchable when this information is needed during an emergency room visit or hospitalization.

Patient characteristics, including CAN score (e.g., 90–94 vs 95–99), gender, type of medical illness, and clinician characteristics (e.g., nurse, social worker, physician assistant, advanced practice nurse, physician) will also be obtained from the VA Corporate Data Warehouse. Practice characteristics, such as primary care team staffing ratios (a measure of the adequacy

of primary care team staffing) and panel capacity (a measure of workload, the percentage of the assigned panel size each primary care clinician is carrying) will be obtained from the VA Support Service Center Capital Assets (VSSC) database.

2.7.3. Analyses—For the primary outcome (goals of care conversation note documented in Stage 2), we will only include patients who did not have a documented goals of care conversation completed during Stage 1 and who were attributed to a physician randomized in Stage 2. We will regress the patient-level binary outcome (note or no note) on indicators of second-stage treatment arm, Stage 1 intervention received, and health system (Denver, Palo Alto, and Los Angeles). Inference will focus on the odds of documentation in Stage 2 using robust standard errors to account for correlation among patients randomized as a panel. As a sensitivity analysis, we will examine whether the rate of documentation changes over time using a "months since Stage 2 start" term in the analysis model.

For secondary outcome 2a, we will regress the patient-level binary outcome (note or no note) inclusive of Stage 1 and 2 on an indicator of Stage 1 treatment arm and health system. Inference will focus on the odds of documentation using robust standard errors to account for correlation among patients randomized as a panel. To test secondary outcome 2b, we will repeat this analysis using the secondary patient-level outcome of note or no note for a patient in Stage 1 of the SMART.

Next, we will compare the four sequences of implementation strategies that are embedded in the SMART design. This analysis will be carried out at the patient level using the intent-to-treat principle. We will use generalized estimating equations with the weighted and replicated approach described by Almirall and Nahum-Shani [32,33] to account for the restricted randomization of non-responder clinician panels in Stage 2. We will perform pairwise tests to compare each of the four embedded regimes. We will report unadjusted *p*-values and p-values adjusted for multiple comparisons using Bonferroni's adjustment.

In exploratory analyses investigating heterogeneity of treatment effect, we will determine whether patient, clinician, and practice characteristics are associated with performance of the sequential implementation strategies in improving completion of goals of care conversation notes. These analyses will be done using the same approach described for the comparison of embedded sequential implementation strategies, including additional model terms for health system and interactions between sequential intervention and potential modifying characteristics. The same comparisons in analyses for the primary and secondary outcomes will be examined for heterogeneity of treatment effect by including interaction terms between these variables and treatment arm. These analyses will be exploratory given we did not power the study to detect interactions.

2.7.4. Sample size—We estimate that we will randomize 50 clinicians that care for 2770 patients, all of whom will meet eligibility criteria. For the primary outcome, we conservatively assumed 3 of 25 (12%) of clinicians in the no patient engagement arm and 7 of 25 (28%) in the low patient engagement arm would have high uptake of notes, giving 40 non-responding clinicians for Stage 2. Assuming a Type 1 error of 0.05 for a two-sided test, an ICC of 0.02, and a rate of documented goals of care of 7% among first-stage

non-responders in the Stage 2 low intensity arm, we will have over 88% power to detect a 7 percentage-point increase in documented goals of care in the high patient engagement arm relative to low patient engagement in Stage 2.

For secondary outcomes 2a and 2b, we assumed $N = 50$ total clinician panels randomized 1:1 to low versus no patient engagement, a Type 1 error of 0.05 for a two-sided test, an ICC of 0.02, and a rate of documented goals of care of 2% within the no patient engagement arm. The 2% rate of documented goals of care is based on preliminary data from 64 clinicians who had at least 15 patients with CAN scores ≥90, obtained from the VA Corporate Data Warehouse during a one-year period. With the assumptions listed above, we will have 88% power to detect a 5 percentage-point increase in documented goals of care in the low patient engagement arm relative to no patient engagement.

2.8. Qualitative evaluation

To understand clinician and patient implementation intervention success or failure, we will use a qualitative evaluation involving clinicians, leaders, patients, and caregivers. The qualitative evaluation will help us understand why and how the clinician and patient implementation intervention succeeded or failed and what the key implementation context domains were at the three study sites. We will also aim to identify barriers and facilitators of trial implementation strategies. This evaluation will help leaders and policy makers translate trial findings into practice across diverse clinic settings. This aim examines the contextual factors that influence the "implementation" outcomes: perspectives on the implementation intervention, recipient characteristics, implementation and sustainability infrastructure, and external environment. If the implementation strategies are not successful, this aim will inform why, e.g., factors related to team function, infrastructure, or the local context. This aim will provide information on how (e.g., distribution of roles/tasks) and in what context primary care can successfully accomplish goals of care conversations in seriously ill Veterans, preparing us for subsequent research and/or dissemination. All interviews will be conducted by an experienced Masters- or PhD-level qualitative researcher. PRISM domains will be used guide development of the qualitative evaluation; guides will be developed during the study to ensure relevance and responsiveness to implementation context.

2.8.1. Organizational interviews—Interviews with at least 12 leaders will be conducted during the study start-up to review the implementation strategies with primary care leaders and clinicians, engage them in the implementation effort, and deepen understanding of the local site context. We will include at least four interviews from each healthcare system sampling from physicians, nursing, social work and leadership. Interview guides are informed by PRISM and the Consolidated Framework for Implementation Research [34].

2.8.2. Clinician interviews—We will interview at least 12 clinicians (MD/NP, nurse and social worker) following stage 2 of the SMART trial, sampling from among the three sites. We will conduct semi-structured telephone interviews with participants to understand their perspectives of the advantages and disadvantages of the implementation strategies and their perceptions of barriers and facilitators to implementation. We will ask

about perceptions of how the team facilitation implementation intervention worked in their local context and compatibility of implementing goals of care conversations with existing programs, resources necessary, process (planning, outreach, facilitation, and engagement), as well as their knowledge, attitudes, and beliefs about the importance of goals of care conversations and if the implementation strategies changed their perspective. Questions will seek to understand the impact on them as individual clinicians as well as on respondent perception of the impact of the intervention on the site and environment. Interviews will be attuned particularly to the PRISM concepts of sustainability and maintenance.

2.8.3. Patient and informal (i.e., Family) caregiver interviews—We will interview at least 20 patients or caregivers staggered throughout the SMART. This is because patients will be sent information about PREPARE and the LSTDI prior to visits with primary care clinicians throughout the study. We will recruit with the intention to interview the Veteran but allow the caregiver to complete the interview if preferred. We will interview Veterans and their caregivers about their perceptions of and experiences with PREPARE and interactions with clinicians around LSTDI. These findings, when triangulated with the clinician interviews will add representation of the patient experiences and preferences and will facilitate translation of trial findings into practice. Results will include Veteran-facing barriers and facilitators to implementation, adoption, and spread from a Veteran perspective.

2.8.4. Qualitative analysis—Interviews will be transcribed verbatim and de-identified. Transcripts will be evaluated using a combined deductive and inductive approach to produce mutually agreed upon themes [35]. As a first step, PRISM domains will be used to inform an a priori code list. Open coding of transcripts will allow for identifying additional emergent themes. Analysis will be an iterative team-based process where qualitative interdisciplinary team meetings will be used to foster consensus for theme development and for resolution of discrepancies. Subsequently, we will use content analysis within each PRISM domain and within additional emergent themes. We will use this approach on organizational leader, clinician, and Veteran/caregiver interviews. Analysis will be conducted using qualitative analytic software ATLAS.ti. Interview data from respondents are collected and analyzed separately by type (e. g. clinician or patient) and then aggregated and triangulated.

2.8.5. Mixed methods analysis—In a convergent mixed methods analysis, the interview results will be triangulated with the findings from Aim 2 to directly compare findings using a matrix approach. In the convergence model, qualitative and quantitative data are collected and analyzed separately, before results on the same phenomenon (e.g., leadership support or adequate primary care staffing level) are “converged” during interpretation.[85] We will use a joint display analysis to support the integration of data sources [36].

Our team engaged with local and National VA leadership to develop appropriate site adapted workflow and implementation strategies for each local context. We track meetings and site-specific trends to document the engagement process throughout the trial. We also document local adaptations using a form and function matrix [37]. Biannual advisory board meetings will be held with local and national leadership and partners. Engagement with patient

advisory boards affiliated with VA occurred during study conceptualization and is planned regularly during the study.

3. Discussion

This study will determine whether a patient and clinician-based implementation intervention to increase goals of care conversations for outpatients at high risk of hospitalization and mortality could be successful with low intensity (requiring fewer resources) versus high intensity implementation strategies. We will also determine what sequence of implementation strategies is best overall and for specific patients or sites. These findings will help health systems decide which implementation strategies to use and when. Increasing goals of care conversations in the outpatient setting will better align medical care with patients' values. This study will test different ways to help providers and patients have discussions in the outpatient setting.

3.1. Study status

The trial completed accrual in September 2022. We are currently providing the sequential implementation strategies.

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Data availability

Data will be made available on request.

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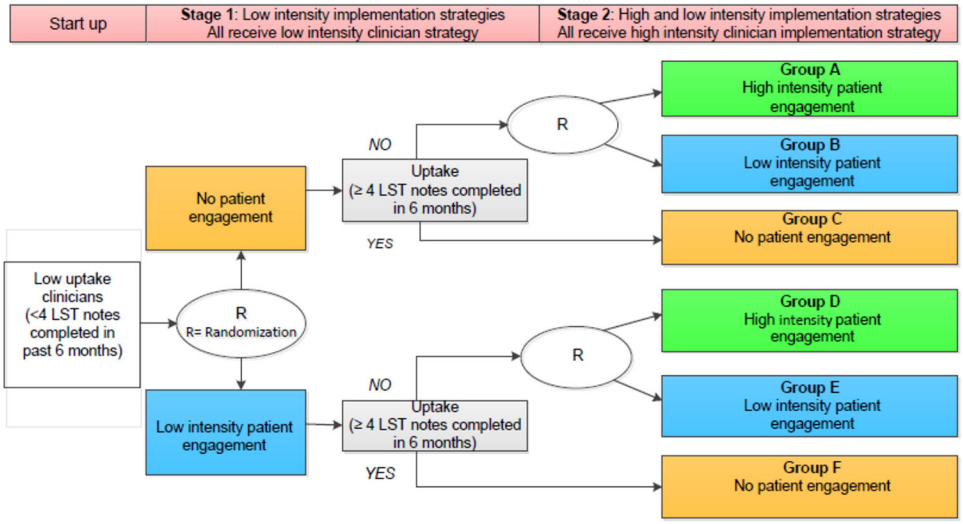

Fig. 1.
Study design

Table 1

Goals of care conversation intervention description [7].

Actors	Physicians, nurses, physician assistants, social workers, chaplains, psychologists
Actions	Elicit and document the patient's values, goals, and preferences as a basis for shared decisions about treatment planning
Target	Patients at high risk of hospitalization or death
Frequency	Within six months of the first outpatient visit *

* Other criteria not relevant to primary care include upon hospitalization or admission to hospice, among others [7].

Table 2

Generalizable knowledge: Design features / innovations

Feature	Innovation, significance, or challenge	Comment	Location in manuscript
Applying a SMART to test implementation strategies	Innovation: Use of SMART to test implementation strategies	SMART generally used for medication and psychotherapy studies to test sequential interventions	Introduction and Methods
Balancing pragmatic approach (point of care, real world) with addressing barriers to implementation	Key challenge: Goal to maximize pragmatism and subsequent uptake of implementation strategies must be balanced with multiple, complex barriers (Table 3) that may require intensive implementation strategies	Research staff provide some of the implementation strategies, such as emailing trigger lists and making phone calls to patients. This approach was chosen given the limited time capacity of primary care.	Methods-implementation strategies
Addressing implementation of established VA policy	Significance: Aligning research with health system operations priorities		Introduction
Addressing both patient and clinician barriers using a participatory approach	- Engaging veteran board - Engaging clinicians, partners and leaders		Methods-implementation strategies

Table 3

Barriers to outpatient goals of care conversations and implementation strategies to address barriers that will be tested in this proposal

Barrier	Target audience	Implementation intervention to address barrier	PRISM domain
Unclear how to identify veterans with serious medical illness with whom to have a goals of care conversation	Clinician	*Clinician* "trigger": notify clinicians of high priority patients for goals of care conversations[a]	Implementation and sustainability infrastructure
Variability in primary care clinician interest and time to conduct goals of care conversation [10–12]	Clinician, organization	*Clinician* Primary care team facilitation with primary care leadership support[a]	Organizational perspective, external environment
Patients are unprepared for goals of care conversations [28]	Patient	*Patient* engagement: PREPARE	Patient perspective

[a]High intensity clinician implementation strategies. The low intensity clinician intervention is described in the Research Design.

Table 4

Clinician implementation intervention description.

	Low intensity	**High intensity (also includes a "nudge": list of eligible patients)**
Actors	Site PI, implementation facilitator and practice director	(same as Low)
Actions	In primary care team meeting: 1. Present written/electronic materials on the LSTDI and review online training options 2. Review when and how to complete goals of care conversations (including tele-visits) and documentation	In primary care team meetings: 1. Engage leadership and champions 2. Model team process and planning 3. Monitor progress and reflect on challenges and successes
Target	Primary care clinicians (MD, APRN, PA) and nurses and social workers	(same as Low)
Frequency and duration	Single, 30–50 min	Three 30- to 40-min meetings
Fidelity monitoring	n, % of clinicians that attend the presentations[a]	(same as Low)

[a]This is a measure of "adoption" in the PRISM model

Table 5

Patient engagement description.

	Low intensity	High intensity
Actors	Research assistant	*Research assistant trained in the LSTDI, PREPARE, and how to discuss them with Veterans*
Actions	Mail letter to Veteran asking them to review the PREPARE website	*Mail letter to Veteran, AND phone call to discuss the purpose of the LSTDI and how PREPARE can help Veterans*
Target	Veterans meeting eligibility criteria	(same as Low)
Temporality	Staggered during the first 3 months	2–4 weeks prior to primary care appointment if possible[c]
Frequency	1 letter per patient sent once	*1 letter per patient sent once, and 1 phone contact or 3 phone call attempts*
Fidelity monitoring	n, % of patients sent a letter (i.e., valid address and letter not returned)[a] n, % of patients who view the PREPARE website[b]	n, % of patients sent a letter[a] n, % of patients who view the PREPARE website[2] n, % of eligible patients called n, % of eligible patients contacted by phone

[a, b] These are measures of "reach" in the PRISM model.

[c] Patients who do not have appointments during the intervention period will be sent letters at random times during the intervention period.